

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BOSTON SCIENTIFIC CORPORATION
and BOSTON SCIENTIFIC SCIMED, INC.,

Plaintiffs,

v.

MICRO-TECH ENDOSCOPY USA INC.,
MICRO-TECH (NANJING) CO., LTD., and
HENRY SCHEIN INC.,

Defendants.

C.A. No. 18-1869-CFC-CJB

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**LETTER TO THE HONORABLE CHRISTOPHER J. BURKE FROM
PILAR G. KRAMAN REGARDING PLAINTIFFS BOSTON
SCIENTIFIC CORPORATION'S AND BOSTON SCIENTIFIC SCIMED, INC.'S
OPPOSITION TO DEFENDANTS' MOTION TO STRIKE
PLAINTIFFS' FINAL INFRINGEMENT CONTENTIONS**

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Dated: August 26, 2020

Redacted Version: September 2, 2020

Dear Judge Burke:

Defendants' motion seeks the extreme sanction of striking BSC's infringement contentions. But, "[t]he exclusion of critical evidence," such as a party's contentions, is "not normally to be imposed absent a showing of willful deception or flagrant disregard of a court order by the proponent of the evidence." *Personal Audio, LLC v. Google, Inc.*, C.A. No. 17-1751-CFC-CJB, 2020 WL 774407, at *1 (D. Del. Feb. 18, 2020) (citation omitted). BSC's contentions are sufficient to satisfy the factors set forth in *Meyers v. Pennypack Woods Home Ownership Assn.*, 559 F.2d 894, 904-05 (3d Cir. 1977), to which Defendants merely pay lip service. BSC responds to each of Defendant's arguments and establishes that Defendants' motion fails under the *Pennypack* factors.

1. BSC's alternative contentions regarding induced infringement are proper

BSC contends that Defendants directly infringe the apparatus claims of the '371 and '725 patents. With respect to the "sheath" limitation, however, BSC asserts, as third-tier alternative argument, that if Defendants do not directly infringe, then the claims are nevertheless infringed by physicians that Defendants induce to infringe. See D.I. 169, Tab 1 at Ex. B, p. 3 and Ex. C, p. 1. Specifically, the limitation recites "a flexible sheath ... which, *in an operative configuration*, extends into a living body" See *id.* (emphasis added). In supplemental interrogatory responses first served on April 30, 2020—*i.e.*, during *Markman* briefing—Defendants asserted for the first time that the accused devices do not infringe because at the time of sale they do not extend into a living body. Ex. A at 14-15. In its contentions, BSC responded that: first, the devices as sold literally satisfy this limitation because they are designed/configured to extend into a patient's body when in use; second, the devices satisfy this limitation under the doctrine of equivalents; and third, to the extent it is determined that the devices do not infringe at the time of sale, they would nevertheless infringe when in use by physicians, and Defendants induce such infringement. BSC submits that it need not formally plead this third-tier alternative argument in an amended complaint given that induced infringement is already at issue in light of BSC's assertions of induced infringement of the method claims of the '245 patent. See D.I. 141 ¶ 37. But, to the extent the Court determines it needs to do so, BSC should be granted leave to amend its complaint.

2. Claim 9 of the '371 patent is properly in the case

"Under *Twombly* and *Iqbal*, the use of exemplary pleading of claims is sufficient to satisfy Rule 12(b)(6)." See *Promos Techs., Inc. v. Samsung Elecs. Co. Ltd.*, C.A. No. 18-307-RGA, 2018 WL 5630585, at *2 (D. Del. Oct. 31, 2018) (citing *Koninklijke Philips N.V. v. ASUSTeK Comput. Inc.*, C.A. No. 15-1125-GMS, 2016 WL 6246763, at *4 (D. Del. Oct. 25, 2016) (holding that providing "specific details of *at least* one of the method and device claims allegedly infringed under each patent-in-suit" was sufficient under Rule 12(b)(6) (emphasis added)). The use of an exemplary claim is permitted particularly "if the allegations in the pleadings are supplemented with detailed infringement contentions," as is the case here. See *Liqwd, Inc. v. L'Oréal USA, Inc.*, C.A. No. 17-14-JFB-SRF, 2019 WL 366223, at *4 (D. Del. Jan. 30, 2019). Thus, BSC was not required to specifically plead each claim it asserts, and the procedural mechanism for identifying the asserted claims is the contentions process set forth in the Court's Scheduling Order.¹ D.I. 29. As such,

¹ Defendants do not challenge BSC's ability to assert claims 3, 7, 13 and 15 of the '245 patent and claims 2, 3, 6, 8, 9, 10, 11, and 12 of the '725 patent, notwithstanding that BSC included detailed allegations in its Amended Complaint only as to claim 1 of each patent.

BSC's Amended Complaint properly includes detailed allegations regarding one asserted, exemplary claim from each of the patents-in-suit. Defendants challenge BSC's right to assert claim 9 of the '371 patent now, but Defendants have been on notice of BSC's contentions as to that claim since at least November 2019, when BSC served its initial infringement contentions.

Defendants ignore the context of the Court's order denying, in part, BSC's motion for leave to amend its complaint. D.I. 136. Some claims of the '371 patent were invalidated in an IPR instituted by a different, unrelated defendant. *See Cook Grp. Inc. v. Boston Sci. Scimed, Inc.*, 809 F. App'x 977 (Fed. Cir. 2020). Thus, when BSC amended its complaint for different reasons, BSC wanted to make clear it was not asserting any of those then-invalidated claims. Accordingly, while including detailed allegations as to representative claim 8, it also specifically identified the particular claims it was still asserting—*i.e.*, only claims 8 and 9. In its order, the Court held that BSC had pled allegations sufficient to satisfy *Iqbal* and *Twombly* only with respect to claim 8 (*i.e.*, and not with respect to claim 9). Accordingly, BSC dropped the references to claim 9 from the Amended Complaint it filed. But as with the other patents-in-suit, BSC did not limit its infringement contentions to just the claim of the '371 patent formally pled in its Amended Complaint. BSC has proceeded in line with the pleading rules and with standard practice in this District for patent cases. Defendants identify no prejudice, nor could they, as they have been on notice of BSC's allegations for more than nine months now. BSC should not be unfairly prejudiced with an extreme sanction for something they were not required to do in the first instance.

3. BSC's contentions provide sufficient notice regarding BSC's infringement theories

Infringement contentions serve a notice function, narrowing the issues and providing a patentee's infringement theories "beyond that which is provided by the mere language of the patent." *See Wi-LAN Inc. v. Vizio, Inc.*, C.A. No. 15-788-LPS, 2018 WL 669730, at *1 (D. Del. Jan. 26, 2018). "Yet Plaintiff need not in its contentions actually prove its infringement case." *Id.* (finding contentions sufficient where plaintiff provided detail regarding how each claim limitation was met by each accused product); *see also Pragmatus Telecom LLC v. Newegg Inc.*, C.A. No. 12-1533-RGA, 2016 WL 675529, at * 3 (D. Del. Feb. 18, 2016) (rejecting defendant's complaints as arguments that "simply nitpick at details it wanted clarified").

Here, Defendants articulate no reasonable basis for striking BSC's infringement contentions or a basis to compel more detail. BSC has fully articulated its infringement positions in its FICs consistent with the Court's claim constructions; Defendants' "disagreement with [BSC's] interpretation of its claims does not make [its] infringement contentions insufficient." *KI Ventures, LLC v. Fry's Elecs., Inc.*, 579 F. App'x 985, 991 (Fed. Cir. 2014). Beyond its contentions, expert discovery will provide further evidence in support of BSC's FICs.

a. BSC's FICs apply the proper claim constructions

Defendants argue that BSC relies on constructions that Judge Connolly rejected for "breakable link...adapted to be broken" and "connecting member." D.I. 169 at 1-2. Not so.

"breakable link ... adapted to be broken": For the "breakable link ... adapted to be broken" limitation of the '245 patent, the highlighted portion of BSC's FICs below (claim 1 of the '245 patent) shows how BSC's FICs faithfully apply the Court's construction:

Court's construction (D.I. 140)	BSC's FICs for '245 patent claim 1 (emphasis added)
"a component of the device designed to mechanically fail by fracturing at a predetermined tensile load"	The Hooks and the proximal pin form a mechanical connection between the control wire and the clip, and that link is a breakable link adapted to be broken in that the Hooks are designed such that, when the control wire retracts and subjects the Hooks <i>to a sufficient tensile force</i> , the connection between the Hooks and the proximal pin is broken, thereby uncoupling the control wire from the clip. The Hooks are designed to mechanically fail by fracturing (e.g., by plastic deformation that causes the Hooks to fracture—see, e.g., BSC-MT139793, -849, and -857) so as to release from the proximal pin upon application of that tensile force.

First, Defendants argue that BSC's contention that "the connection between the Hooks and the proximal pin is broken, thereby uncoupling the control wire from the clip" is "the claim construction position Plaintiffs proposed and the Court rejected." D.I. 169 at 2. But BSC does not contend that "the connection" is the only thing that breaks. Rather, BSC contends that the connection between the Hooks and the proximal pin breaks because the Hooks themselves break. See, e.g., D.I. 169, Tab 1 at Ex. A, p. 2 ("The Hooks are designed to mechanically fail by fracturing....").

Second, Defendants argue that BSC's FICs "merely suggest[] that this claim element may be met 'e.g.,' when a component undergoes deformation, a point that Judge Connolly also expressly rejected." D.I. 169 at 2. But BSC contends that fracturing occurs not just by any form of deformation, but specifically by *plastic deformation that results in fracturing* of the accused devices' Hooks. Unlike other forms of deformation, which the Court likened to "straightening" (see D.I. 169, Tab 2 (Hrg. Tr.) at 33:1-2) and do not result in mechanical failure by fracturing, plastic deformation permanently distorts the material when subjected to stress that exceeds its yield strength, causing it to, in some instances, mechanically fail by fracturing. This contention is consistent with the Court's construction. See *id.* at 34:11-16. This type of fracturing is described in the documents explicitly referenced in BSC's FIC's, including an expert report submitted in European infringement litigation between the parties involving foreign counterparts of the patents-in-suit. Ex. B.

Third, BSC specifically contends that the Accused Devices are *designed* to mechanically fail by fracturing—again consistent with the Court's construction, and which Defendants explicitly admit in their submissions to the FDA seeking clearance to market the Accused Devices. See Ex. C at 4 ("[REDACTED]") (emphasis added); D.I. 169, Tab 2 (Hrg. Tr.) at 34:23-35:5.

"connecting member": Likewise, for the "connecting member" limitation of the '725 patent, BSC's FICs again faithfully apply the Court's construction:

Court's construction (D.I. 140)	BSC's FICs for '725 patent claim 1
<p>“tension member that connects the clip arms to the yoke and biases the clip arms to an open configuration”</p>	<p>As just described, for the Accused Original/Buckle Devices, the Hooks and connecting tube form a separable yoke. The Hooks extend distally from the control member on opposite sides of the clip assembly and hook onto the proximal pin on opposite sides of the clip. The proximal pin thus extends between the first and second yoke arms coupling the yoke to the clip assembly. The proximal pin is a tension member that connects the clip arms to the yoke and biases the clip arms to an open configuration. Distal movement of the control wire causes the proximal pin to move distally, and the distal movement of the proximal pin causes the clip arms to open as the clip arms are pushed out of the capsule and the slots formed in the proximal section of the clip arms ride against the distal pin. Thus, the proximal pin biases the clip arms in the open position. The yoke arms become separated from the proximal pin when subjected to a predetermined force by the control member to uncouple the control member from the clip assembly as is described in detail above.</p>

In particular, BSC's FICs state that the proximal pin is the tension member—the tension comes from the fact that the proximal pin is a solid component that establishes a resistive force so that the yoke can separate from it under the tension force applied by the control element. The term “bias” means “a force field applied to a device to establish a reference level to operate the device.” Ex. D. Here, the reference level is the arms-open position, which is attained by the force of the control wire on the proximal pin (*i.e.*, the tension member) when the control wire pushes the proximal pin distally. Thus, the proximal pin is a “connecting member” in accordance with the Court's construction. Moreover, BSC has included alternative contentions as to how the Accused Devices satisfy this limitation under the doctrine of equivalents. *E.g.*, D.I. 169, Tab 1 at Ex. C, p. 6.

Unlike the contentions at issue in *Intellectual Ventures I LLC v. AT&T Mobility LLC*, C.A. No. 13-1668-LPS, 2017 WL 658469 (D. Del. Feb. 14, 2017) (“*IV*”), BSC's contentions apply the Court's claim constructions and put Defendants on notice as to how the accused products meet the asserted claim limitations. The Court struck the contentions in *IV* because those contentions omitted “the latter half of the Court's construction,” which the Court found “problematic because, as the Court observed in its claim construction opinion, application-awareness requires both parts of the Court's construction.” *IV* at *2. Here, by contrast, BSC faithfully applied the Court's constructions to each Accused Device, providing notice to Defendants of BSC's infringement theories. Defendants may disagree with BSC's positions regarding application of the Court's claim constructions to these devices, but those disagreements have no bearing on the sufficiency of the contentions themselves and will “be adjudicated, on the merits, at the appropriate time.” *Princeton Digit. Image Corp. v. Harmonix Music Sys., Inc.*, C.A. No. 12-1461-LPS-CJB, 2018 WL 2298340, at *4 (D. Del. May 14, 2018).

b. BSC's FICs provide sufficient notice as to its theories regarding the '245 patent

Defendants wrongly assert that BSC's FICs for the '245 patent are deficient as to the Accused Buckle and Lockado Devices because they purportedly allege that some "unidentified component fractures" and cite no evidence "of which, if any, component actually fractures." D.I. 169 at 3. BSC clearly identifies the components *that fracture*: the Lockado devices' "C-shaped Hooks [that] extend proximally from the clip legs," and the Buckle devices' "C-shaped (buckle) hooks [that] extend distally from a connecting tube coupled to the distal end of the control wire." D.I. 169 at Tab 1, Ex. A, pp. 2-3. BSC further identifies *how* these Hooks satisfy the limitation—they are each "designed to mechanically fail by fracturing (e.g., by plastic deformation that causes the Hooks to fracture). . . . A tensile force sufficient to cause the breakable link to break in this manner is applied when the user exerts a tensile force on the control wire and this force is opposed by a corresponding oppositely directed force via the coil shaft, the bushing, and the capsule." *See* discussion *supra* regarding the "breakable link . . . adapted to be broken" limitation. As discussed above, and as BSC's expert will demonstrate, the plastic deformation resulting in fracturing of these Hooks is sufficient to satisfy the Court's construction and occurs in the same fashion as occurs with respect to the j-hooks of the Accused Original Device. Contentions are not the time for BSC to put forth all of its evidence, or even any evidence, of Defendants' infringement; that is for expert discovery. *See Wi-LAN*, 2018 WL 669730, at *1.

c. BSC's Doctrine of Equivalents ("DOE") contentions provide sufficient notice

Defendants mischaracterize BSC's DOE contentions as being cursory and merely reserving the right to assert infringement based on DOE. D.I. 169 at 3. Not so. In reality, for each relevant limitation, BSC specifies why the accused component is insubstantially different from the claim element, and further applies the well-established "function-way-result" analysis. *E.g.*, D.I. 169, Tab 1 at Ex. C, pp. 5-6. These are far from boilerplate reservations of the right to assert DOE, and they clearly disclose BSC's DOE theories.

The single case Defendants cite—*IV*, 2017 WL 658469—supports BSC, not Defendants. Although the Court found certain of IV's DOE contentions lacking where they relied on an incorrect claim construction (*id.*, at *2), it affirmed the sufficiency of other DOE contentions that "establish equivalency on a limitation-by-limitation basis, 'linking . . . the insubstantiality of differences between the claimed invention and the accused device' and, as a result provide sufficient notice of IV's DOE theory." *Id.* (quoting *Akzo Nobel Coatings, Inc. v. Dow Chem. Co.*, 811 F.3d 1334, 1342 (Fed. Cir. 2016)). That is exactly what BSC's DOE contentions do here.

* * *

Finally, Defendants assert no cognizable claim of prejudice. They are on notice of BSC's infringement theories, and BSC's experts will apply the Court's claim constructions in their reports, as BSC has done in its FICs. At the very least, if the Court finds that BSC's contentions are in any way deficient, it should grant BSC the opportunity to amend its contentions, rather than having them struck altogether. While Defendants fail to address any of the other *Pennypack* factors, BSC notes that the trial is not until next year, and no expert reports have been served. Further, Defendants do not allege, nor could they prove, any bad faith or willfulness on BSC's part.

For all of these reasons, the Court should deny Defendants' motion.

Respectfully,

/s/ Pilar G. Kraman

Pilar G. Kraman (No. 5199)

Attachments: Exhibits A-D

CERTIFICATE OF SERVICE

I, Pilar G. Kraman, Esquire, hereby certify that on September 2, 2020, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF (which will send notification that such filing is available for viewing and downloading to all registered counsel), and in addition caused true and correct copies of the foregoing document to be served upon the following counsel of record by electronic mail:

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